As Applicants have explained above, the examiner's assertions regarding the 04462 application are misdirected and a person of skill in the art who had read Gillies and the 04462 application would not find it obvious to use the cDNA encoding the entire constant and variable regions of the heavy and light chains of an antibody in expression vectors for the production of a recombinant antibody. As Larrick does not compensate for the deficiencies of these two references, claim 11 is not obvious.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims of this application are in condition for allowance.

Respectfully submitted,

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STATUS OF THE CLAIMS

PENDING: 1-14
CANCELLED: 15-31

15. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Applicants' cancellation of Figure 1 is noted and is not deemed to introduce new matter. Applicants' request to hold in abeyance the formal drawing requirements is noted.

16. Claims 1-14 were rejected under 35 U.S.C. § 101 because the invention as disclosed is inoperative and therefore lacks utility. This rejection has been withdrawn in view of Applicants' arguments.

17. Claims 1-14 were rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification (paragraph 19A, paper #15). This rejection has been withdrawn in view of the utility of the invention as a diagnostic aid.

18. Claims 1-14 stand rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the use of the claimed invention as a diagnostic aid or as a therapeutic agent. Applicant does not appear to have traversed this grounds of rejection. The specification fails to adequately teach how to use (i.e. provide a written description on how to use) the antibodies made in accordance with the claimed invention as diagnostic aids. A single sentence stating, in passing, that the antibodies rescued in accordance with the claimed invention is not sufficient to enable the use of said antibodies in general diagnostic assays.

19. Claims 1-2, 4-5, 7-10, 12-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gillies et al. Gillies et al. teach methods for the production of human (primate) antibodies (specifically anti-tetanus antibodies) from cDNA libraries, as well as transfected cell lines, transfecting vectors, and a recombinant human (primate antibody that would be useful for the treatment of tetanus poisoning (see Materials and Methods). Applicant argues that the specification teaches the cloning and insertion of the entire cDNA sequence encoding the heavy and light chain of immunoglobulin molecules into a vector. No such claim limitation exists. Applicants' arguments appear to cover critical features of the invention that are not claimed. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the

time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. For this reason, Applicants' arguments are not found persuasive.

20. Claim 31 is rejected under 35 U.S.C. § 102(b) as being anticipated by Harris et al. (EP 314161). This rejection is now moot in view of the cancellation of the claimed subject matter.

21. Claims 3 and 6 stand rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. in view of Foung et al. (WO 87/01131) and Ehrlich et al. Applicant traverses on the grounds that Gillies et al. teach away from the claimed invention in that the insertion of intact cDNA is not taught. Applicant would appear to be arguing claim limitations not present. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. Applicants' arguments have been considered but are not found persuasive.

22. Claim 11 stands rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. in view of Larrick et al. The claim is drawn to a method for the production of recombinant antibodies using micro-preps of RNA. Applicant argues that Gillies et al. requires the use of genomic DNA encoding the heavy chain of Ig molecules. Applicants' arguments appear to be directed to unclaimed elements believed to define over the prior art. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. No such limitations exist in the claims, accordingly applicants' arguments are not found persuasive.

23. Claim 25 was rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. in view of Foung et al. (WO 87/01131), Ehrlich et al. and Harris et al. (EP 314161). This rejection is moot in view of the cancellation of the claims.

24. No claim is allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

25. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CMI Fax Center telephone number is (703) 308-4227.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Eisenschenk whose telephone number is (703) 308-0452. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

Christopher Eisenschenk, Ph.D.
May 26, 1994

DAVID L. LACEY
SUPERVISORY PATENT EXAMINER
GROUP 180
5/27/94